

wherein the cancer is a cancer selected from the group consisting of breast cancer, colorectal cancer, gastric cancer, esophageal cancer, Burkitt's lymphoma, B follicular cell lymphoma and small cell lung carcinoma.

36. The method of claim 35 wherein the cancer is colorectal cancer.

37. The method of claim 36 wherein determining the genomic polymorphism of the subject comprises determining the subject's genotype at a tandemly repeated 28 base pair sequence in the thymidylate synthase (TS) gene's 5' untranslated region (UTR), wherein the genotype is homozygous for a triple repeat of the tandemly repeated sequence, heterozygous for a double repeat and a triple repeat of the tandemly repeated sequence, or homozygous for a double repeat of the tandemly repeated sequence.

38. The method of claim 37 wherein the chemotherapeutic drug is a TS directed drug.

39. The method of claim 38 wherein the TS directed drug is a fluoropyrimidine.

40. The method of claim 39 wherein the fluoropyrimidine is 5-fluorouracil.

41. The method of claim 40 wherein the subject is a human subject.

42. The method of claim 41 wherein determining the subject's genotype further comprises:
extracting genomic DNA from a biological sample of the subject;
amplifying the 5' UTR of the thymidylate synthase gene of said genomic DNA using polymerase chain reaction; and
analyzing the polymerase chain reaction product to determine the subject's genotype.

43. The method of claim 45 wherein analysis of the polymerase chain reaction product is performed using electrophoresis.

1 44. A method for the treatment of a cancer in a subject, the method comprising:
 2 (a) determining the subject's genotype at a tandemly repeated 28 base pair sequence in
 3 the thymidylate synthase gene's 5' UTR, wherein the subject's genotype is homozygous
 4 for a triple repeat of the tandemly repeated sequence, heterozygous for a double repeat
 5 and a triple repeat of the tandemly repeated sequence, or homozygous for a double repeat
 6 of the tandemly repeated sequence, and
 7 (b) administering a TS-directed drug to the subject if the subject's genotype is
 8 homozygous for a double repeat of the tandemly repeated sequence,
 9 wherein the cancer is a cancer selected from the group consisting of breast cancer,
 10 colorectal cancer, gastric cancer, esophageal cancer, Burkitt's lymphoma, B follicular cell
 11 lymphoma and small cell lung carcinoma.

1 45. The method of claim 44 wherein determining the subject's genotype further comprises:
 2 extracting genomic DNA from a biological sample of the subject;
 3 amplifying the 5' UTR of the thymidylate synthase gene of said genomic DNA using
 4 polymerase chain reaction; and
 5 analyzing the polymerase chain reaction product to determine the subject's genotype.

1 46. The method of claim 45 wherein analysis of the polymerase chain reaction product is
 2 performed using electrophoresis.

1 47. A method for determining the suitability of treating a cancer in a subject using a
 2 chemotherapeutic drug, the method comprising:
 3 taking a biological sample of the subject; and
 4 using the biological sample to determine the genotype of a gene of the subject,
 5 wherein said genotype determines the intratumoral expression of said gene, and wherein
 6 said gene expression determines the response of the subject to said chemotherapeutic
 7 drug.

1 48. The method of claim 47 wherein the cancer is colorectal cancer.

Continued

- 1 49. The method of claim 48 wherein the gene is thymidylate synthase gene.
- 1 50. The method of claim 49 wherein determining the genotype comprises determining the
2 subject's genotype at a tandemly repeated 28 base pair sequence in the thymidylate
3 synthase (TS) gene's 5' untranslated region (UTR), wherein the genotype is homozygous
4 for a triple repeat of the tandemly repeated sequence, heterozygous for a double repeat
5 and a triple repeat of the tandemly repeated sequence, or homozygous for a double repeat
6 of the tandemly repeated sequence.
- 1 51. The method of claim 50 wherein the chemotherapeutic drug is a TS directed drug.
- 1 52. The method of claim 51 wherein the TS directed drug is a fluoropyrimidine.
- 1 53. The method of claim 52 wherein the fluoropyrimidine is 5-fluorouracil.
-
- 1 54. The method of claim 53 wherein the subject is a human subject.
- 1 55. The method of claim 54 wherein determining the subject's genotype further comprises:
2 extracting genomic DNA from a biological sample of the subject;
3 amplifying the 5' UTR of the thymidylate synthase gene of said genomic DNA using
4 polymerase chain reaction; and
5 analyzing the polymerase chain reaction product to determine the subject's genotype.
- 1 56. The method of claim 55 wherein analysis of the polymerase chain reaction product is
2 performed using electrophoresis.
- 1 57. A kit for use in screening for the effectiveness of TS directed drug therapy in human
2 subjects, the kit comprising:
3 means for determining a genomic polymorphism of the TS gene; and
4 instructions for use of the kit.
- 1 58. The kit of claim 57 wherein the means for determining said genomic polymorphism
2 comprise: